REMARKS

The Invention

Applicants' invention is drawn to DNA sequences encoding a biologically functional eukaryotic acetohydroxy-acid synthase (AHAS) protein and functional variants thereof. In particular, the invention discloses the DNA sequences of the *Arabidopsis* AHAS gene and cDNA, as well as the amino acid sequence of the AHAS small subunit protein encoded thereby. The invention further discloses methods for using such DNA sequences to enhance the herbicide resistance of plants and plant cells. Additionally, the invention provides isolated DNA sequences encoding other eukaryotic AHAS small subunit proteins, isolated eukaryotic AHAS small subunit proteins, plant expression vectors, and transformed plants and progeny thereof.

Priority

The Office Action indicates that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120. First, the Office Action indicates that parent Application No. 09/426,568, filed October 22, 1999, does not provide adequate support under 35 U.S.C. § 112, first paragraph, for the negative limitation in claim 1. Second, while acknowledging Applicants' claim for domestic priority under 35 U.S.C. § 119(e), the Office Action indicates that the priority application, provisional Application No. 60/106,239, does not provide adequate support under 35 U.S.C. § 112, first paragraph, for the negative limitation in claim 1.

Claim 1 has been amended to delete the negative limitation therein. The negative limitation is not recited in any other claim, including the original claims, currently amended claims and the new claims. Accordingly, it is submitted that the application as amended is in compliance with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 and domestic priority under 35 U.S.C. § 119(e).

The Objection to the Specification Should Be Withdrawn

The specification has been objected to for not indicating in the priority statement that the parent application has issued as a patent. The Office Action indicates that, because parent Application No. 09/426,568 has issued as U.S. Patent No. 6,348,643, the priority statement must be amended to reflect the status of the parent application.

As set forth above, the specification has been amended on page 1, paragraph 1, to indicate the status of the Application No. 09/426,568. In addition, the first paragraph on page 1 has been amended to insert --35-- immediately in before "U.S.C." in the first sentence to properly reflect the complete citation for the statute referred to therein. In the Preliminary Amendment dated November 30, 2001, Applicants previously amended this paragraph. At that time, however, Applicants inadvertently omitted the reference to the relevant chapter of the United States Code.

These amendments to the specification are purely formal in nature. Accordingly, no new matter has been added by way of amendment of the specification.

In view of the amendment of the specification, the objection to the disclosure should be withdrawn.

Additional Amendments to the Specification

Upon review of the instant specification, an omission of an article and a typographical error were discovered in the last paragraph on page 41. In the first sentence of this paragraph, --the-- was inserted immediately before "present invention". Also, in this same sentence, the word "astringent", which is immediately before "DNA hybridization" was replaced with the correct term --stringent--. These amendments to the specification are purely formal in nature and do not constitute new matter.

Status of the Claims

Claims 15-21 have been cancelled without prejudice or disclaimer. Claims 15-21 are drawn to non-elected subject matter and had been withdrawn by the Examiner in the instant

Office Action. Applicants expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the cancelled claims.

Claim 1 has been amended to clarify the Applicants claimed invention is drawn to isolated DNA sequences encoding biologically functional eukaryotic AHAS small subunit proteins that hybridize to the SEQ ID NO:1 under conditions comprising: (a) hybridization at 42°C for 20 hours in a solution comprising 50% formamide, 2X SSC, 5X Denhardt's solution, 1% sodium dodecyl sulfate (SDS), 0.05 mg/ml denatured salmon sperm DNA, and 0.05% NaPPi; (b) two washes at room temperature for 10 minutes in a solution comprising 0.4X SSC and 0.1% SDS; and (c) one wash at 65°C for 30 minutes in a solution comprising 0.2X SSC and 0.1% SDS. Support for the amendment to claim 1 can be found in the specification particularly on pages 6, 33, and 41.

New claims 22-25 have been added. The new claims are drawn to plants and progeny thereof whose genetic complement comprises a plant expression vector, which comprise a promoter expressible in a plant cell operably linked to a DNA sequence encoding an *Arabidopsis* AHAS small subunit protein. Support for the new claims can be found in the specification, particularly on pages 6, 7, 10, 13, and 41.

No new matter has been added by way of amendment of the claims or by the addition of the new claims.

Claims 1-14 and 22-25 are pending.

Reexamination and reconsideration of the application as amended are respectfully requested.

The Rejection of the Claim 13 under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claim 13 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Claim 13 has been amended. This rejection is respectfully traversed.

The Office Action indicates that it is unclear what the metes and bounds of claim 13 are because the phrase "a DNA sequence" at claim line 2 may be directed to a an isolated DNA

sequence or an endogenous DNA sequence. Applicants have amended claim 13 to recite that the DNA sequence is "an isolated DNA sequence" as suggested on page 11 of the Office Action. As amended, the claim is not indefinite.

In view of the amendment and remarks, it is submitted that the rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn.

The Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 1-5 and 13 have been rejected under 35 U.S.C. § 112, first paragraph. Claims 1 and 13 have been amended. New claims 22-25 have been added. This rejection is respectfully traversed and should not be applied to the newly submitted claims.

Claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter which was not described in the specification in a such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention. The Office Action indicates that Applicants describe an isolated DNA molecule encoding an AHAS small subunit protein having the sequence of SEQ ID NO: 1 that encodes the sequence of SEQ ID NO:2 but do not describe other isolated DNA molecules encoding a eukaryotic small subunit protein, not known in the art at the time of Applicant's invention. The Office Action discusses the holding of *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) and concludes that Applicants have only described a single species of the claimed genus/subgenus, and do not describe structural features common to the members of the claimed genus, only their function.

Claim 1 has been amended, as *Lilly* requires, to recite both the functional and structural features of the claimed isolated DNA sequences. As amended, claim 1 recites that the claimed isolated DNA sequences encode biologically functional eukaryotic AHAS small subunit proteins that hybridize to the complement of the sequence set forth in SEQ ID NO:1 under defined hybridization and wash conditions. The specification provides adequate description of the subject matter of amended claim 1 and its dependent claims so as to reasonably convey to one

skilled in the relevant art that Applicants had possession of the invention as claimed. In particular, the specification discloses on page 6 that the invention encompasses "DNA sequences encoding a biologically functional eukaryotic AHAS small subunit protein and functional variants thereof." Furthermore, the specification indicates on page 41 that homologous AHAS small subunit gene sequences can be obtained from a variety of plant species using stringent DNA hybridization techniques. The specification further discloses specific hybridization conditions that can be used to isolate such homologous sequences on page 33. Accordingly, the subject matter of amended claim 1 and its dependent claims is adequately described in the instant specification so as to reasonably convey to one of ordinary skill in the relevant art that, at the time of the invention, Applicants had possession of the claimed invention.

Claims 1-5 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Office Action indicates that the specification is enabled for an isolated DNA sequence encoding a eukaryotic AHAS small subunit protein having the sequence of SEQ ID NO: 1 or encoding the amino acid sequence of SEQ ID NO: 2, expression vectors comprising said isolated DNA sequence and transgenic plants comprising said expression vector. The Office Action, however, asserts the Applicants, do not teach other isolated DNA molecules encoding a eukaryotic AHAS small subunit protein, not known in the art at the time of Applicant's invention. The Office Action cites Duggleby *et al.* as teaching that the ultimate function of any DNA sequence, whose identity is based solely on homology, can only be proven in experiments designed to evaluate that the function. The Office Action concludes that the specification does not enable any person skilled in the art to which it pertains to, or with which is most nearly connected, to make and use the invention commensurate with the scope of the claims.

As discussed above, claim 1 has been amended to recite that the claimed isolated DNA sequences encode biologically functional eukaryotic AHAS small subunit proteins that hybridize to the complement of the sequence set forth in SEQ ID NO:1 under defined hybridization and wash conditions. In contrast to the Examiner's conclusions, the specification provides sufficient guidance to make and identify the isolated DNA sequences encompassed by the claims. In particular, Applicants have provided the DNA sequence of SEQ ID NO: 1. The claimed DNA

sequences vary from this sequence by structural parameters (*i.e.*, hybridization to the complement of SEQ ID NO:1 under defined hybridization and wash conditions). While DNA hybridization is a technique that is within the knowledge of one of ordinary skill in the art, additional guidance for DNA hybridization is set forth in the specification on pages 32-33.

Moreover, the DNA sequences of the invention encode biologically functional eukaryotic AHAS small subunit proteins. Such DNA sequences molecules include those that are fragments and variants of SEQ ID NO: 1 and that encode biologically functional eukaryotic AHAS small subunit proteins. Methods for assaying whether the DNA sequences encode biologically functional eukaryotic AHAS small subunit proteins are known in the art and are also provided in the instant specification on pages 19-20, 34-38 (Example 2), and 39-41 (Example 4). Accordingly, based on the guidance in the specification, one of skill in the art would be able to determine which DNA sequences are encompassed by the present invention.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation needed to practice the invention is not undue. *In re Wands* 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Furthermore, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.*

Applicants stress that when evaluating the quantity of experimentation required, the court looks to the amount of experimentation required to practice a single embodiment of the invention, rather than the amount required to practice every embodiment of the invention. For example, in *Wands*, the claims at issue were drawn to immunoassay methods using any monoclonal antibody having a binding affinity for HbsAg of at least 10-9 M. The PTO had taken the position that the claim was not enabled as it would take undue experimentation to make the monoclonal antibodies required for the assay. The Federal Circuit reversed, and held that the claims were enabled, as the amount of experimentation required to isolate monoclonal antibodies and screen for those having the correct affinity was not undue. *Id.* Clearly, the Federal Circuit did not contemplate that every antibody useful in the methods of the claim must be identified.

Rather, the court considered the amount of experimentation required to identify one or a few monoclonal antibodies having the required affinity.

In the instant case, the quantity of experimentation required to practice the invention amounts to two steps, identifying a DNA sequence that hybridizes to the complement of SEQ ID NO:1 under the hybridization and wash conditions that are recited in claim 1 and then assaying for functional activity. Thus, ample guidance is provided to allow one of skill in the art to identify additional DNA sequences encompassed by claim 1 and dependent claims 2-5. Consequently, contrary to the Examiner's conclusions, the quantity of experimentation necessary and the amount of guidance presented in the specification is sufficient to enable the claimed DNA sequences of the invention as set forth in claim 1.

Claim 13 has been rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabled for a transgenic plant whose genetic complement comprises a heterologous promoter expressible in a plant cell operably linked to an isolated DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein, does not reasonably provide enablement for a transgenic plant whose genetic complement comprises a heterologous promoter expressible in a plant cell operably linked to a DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein that is endogenous to said plant. The Office Action goes on to clarify that the specification does not enable the incorporation of said heterologous promoter in an operable linkage with the coding sequence of the target endogenous coding sequence of an *Arabidopsis* AHAS small subunit protein. The Office Action indicates that the rejection of claim 13 would be obviated by amendment of the claim to read --operably linked to an isolated DNA sequence--.

As discussed above, claim 13 has been amended to clarify that the DNA sequence is "an isolated DNA sequence" as suggested in the Office Action. Accordingly, the objection to claim 13 is obviated.

Additionally, Applicants note for the record that amended claim 13 encompasses a transgenic *Arabidopsis* plant whose genetic complement comprises a heterologous promoter

expressible in a plant cell operably linked to an isolated DNA sequence encoding a small subunit of an *Arabidopsis* AHAS protein.

In view of the amendments and remarks, it is submitted that the rejections under 35 U.S.C. § 112, first paragraph, should be withdrawn and should not be applied to the newly submitted claims.

The Rejection of the Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-5 have been rejected under 35 U.S.C. § 103 as being unpatentable over Abell *et al.* (WO 98/37206). Claim 1 has been amended. New claims 22-25 have been added. This rejection is respectfully traversed and should not be applied to the newly submitted claims.

The Office Action indicates that Applicants claim an isolated DNA sequence encoding a eukaryotic AHAS small subunit protein wherein said DNA sequence is not isolatable from *Nicotiana plumbaginifolia* or maize, and a plant expression vector comprising said DNA sequence. The Office Action further indicates that Abell *et al.* discloses the DNA sequences encoding AHAS small subunit proteins isolated from *Nicotiana plumbaginifolia* and maize, expression vectors comprising such DNA sequences, and that expression of the AHAS small subunit protein can include plants transformed with an AHAS small subunit protein. The Office Action asserts claims 1-5 are *prima facie* obvious because Abell *et al.* teaches two species within the claimed genus.

As discussed above, claim1 has been amended to delete the negative limitation, which excluded from the scope of the claim DNA sequences that are isolatable from *Nicotiana plumbaginifolia* or maize. Claim 1 has also been amended to clarify that the claimed isolated DNA sequences encode biologically functional eukaryotic AHAS small subunit proteins that hybridize to the complement of the sequence set forth in SEQ ID NO:1 under defined hybridization and wash conditions. In view of this amendment, claim 1 and dependent claims 2-5 are not obvious in view of the teachings of Abell *et al.* for the following reasons. First, Abell *et al.* fails to teach or even suggest an isolated DNA sequence that encodes an *Arabidopsis* AHAS small subunit protein, wherein said DNA sequence has the sequence set forth in SEQ ID

NO:1. Second, Abell *et al.* fails to teach or even suggest an isolated DNA sequence that encodes a biologically functional eukaryotic AHAS small subunit protein, wherein said DNA sequence hybridizes to the complement of the sequence set forth in SEQ ID NO:1 under the hybridization and wash conditions recited in amended claim 1. Thus, the teachings of Abell *et al.* do not render obvious Applicants' claimed invention.

In view of the amendment and remarks, it is submitted that the rejections under 35 U.S.C. § 103 should be withdrawn and not applied to the newly submitted claims.

The Rejection of the Claims for Double Patenting Should Be Withdrawn

Claims 1–14 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, and 23 of U.S. Patent No. 6,348,643. Claims 1 and 13 have been amended. New claims 22-25 have been added. This rejection is respectfully traversed and should not be applied to the newly submitted claims.

Applicants submit concurrently herewith a terminal disclaimer compliant with 37 C.F.R. § 1.130(b). In view of the terminal disclaimer and the above remarks, it is submitted that the rejections of the claims under the judicially created doctrine of obviousness-type double patenting should be withdrawn and not applied to the newly submitted claims.

CONCLUSIONS

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§ 103 and 112 and the judicially created doctrine of obviousness-type double patenting are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. In any event, the Examiner is respectfully requested to enter the above amendments for the purpose of furthering prosecution.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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